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09/600,012	09/06/2000	Jeffrey Owen Phillips	CUMP.75681	7874

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EXAMINER

KREMER, MATTHEW J

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 02/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/600,012

Applicant(s)

PHILLIPS ET AL.

Examiner

Matthew J Kremer

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Specification*

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

2. The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-Reference to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. 35 U.S.C. 101 reads as follows:

Art Unit: 3736

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 7 provides for the use of the measured changes of CSF pH with time in diagnosis or therapy of neurological injuries, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Claim 8 provides for the use of means for monitoring the change of CSF pH with time in the manufacture of apparatus for diagnosing the outcome of blunt head trauma, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Claim 9 provides for the use of means for monitoring the change of CSF pH with time in the manufacture of apparatus for the therapy of blunt head trauma, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

Art Unit: 3736

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

7. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claim 1 recites the limitation "the outcome" in line 1 in which there is insufficient antecedent basis. To correct the problem, the limitation should be written "an outcome." Claim 4 recites the limitation "the measured pH" in line 1 in which there is insufficient antecedent basis. To correct the problem, the limitation should be written "the monitored pH." Claim 5 recites the limitations "the change of cerebrospinal fluid pH" in line 2 and "the patient" in line 4 in which there are insufficient bases. Claim 6 recites the limitations "the calculated pH values" in line 7 and "the resulting values" in line 9 in which there are insufficient antecedent bases. Claim 7 recites the limitation "the measured changes" in line 1 in which there is insufficient antecedent basis. Claim 8 recites the limitations "the change of CSF pH" in line 1 and "the outcome" in line 2 in which there are insufficient antecedent bases. Claim 9 recites the limitations "the change of CSF pH" in line 1 and "the therapy" in line 2 in which there are insufficient antecedent bases.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3736

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,904,237 to Janese. Janese discloses an apparatus and method for exchanging cerebrospinal fluid. The apparatus treats disease states by filtration, cooling, adjusting hydrogen ion concentration and returning the cerebrospinal fluid or artificial cerebrospinal fluid to the spinal canal. This apparatus and procedure can be used in any vertebrate for the treatment of brain and spinal cord injuries. Furthermore, the apparatus and method can be used for monitoring the current status of a patient by monitoring the physical and chemical parameters of the cerebrospinal fluid. (column 1, lines 7-17 of Janese). The apparatus monitors cerebrospinal fluid pH. (column 2, lines 29-39 of Janese). The injuries that can be treated include intra-cranial arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage. (column 10, lines 23-35 of Janese). In regards to claim 8, Janese teaches that the pH and other parameters are monitored to detect any dangerous or significant changes in the medical management of the patient. These changes alert the technician that something is wrong with the system or the patient which requires immediate attention. (column 8, lines 50-60 of Janese). The system alerts the technician because the outcome of the head trauma will result in the patient's death without immediate attention.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,904,237 to Janese. Janese discloses an apparatus and method for exchanging cerebrospinal fluid. The apparatus treats disease states by filtration, cooling, adjusting hydrogen ion concentration and returning the cerebrospinal fluid or artificial cerebrospinal fluid to the spinal canal. This apparatus and procedure can be used in any vertebrate for the treatment of brain and spinal cord injuries. Furthermore, the apparatus and method can be used for monitoring the current status of a patient by monitoring the physical and chemical parameters of the cerebrospinal fluid. (column 1, lines 7-17 of Janese). The apparatus monitors cerebrospinal fluid pH. (column 2, lines 29-39 of Janese). The injuries that can be treated include intra-cranial arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage. (column 10, lines 23-35 of Janese). Janese does not disclose monitoring within the initial 24 hours of the trauma. It is known in the art that the monitoring and treatment of patients after a trauma is routinely performed to improve the patient's chances for survival. The patient's survival will particularly increase if monitoring and treatment are initiated as soon possible after the trauma. Therefore, it

Art Unit: 3736

would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of Janese to include initiating monitoring and treatment within 24 hours from the head trauma since the immediate attention will improve the patient's chances for survival. In regards to claim 1, Janese teaches that the pH and other parameters are monitored to detect any dangerous or significant changes in the medical management of the patient. These changes alert the technician that something is wrong with the system or the patient which requires immediate attention. (column 8, lines 50-60 of Janese). The system alerts the technician because the outcome of the head trauma will result in the patient's death without immediate attention. In regard to claim 3, the probe is received in the ventricle of the patient. (Figs. 4-6 of Janese). In regard to claim 4, the alarm for any parameter, including pH, is sounded when that parameter falls below a pre-determined threshold. (column 9, lines 18-30 of Janese). The factors to determine thresholds include those conditions of the patient to be avoided including death.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,904,237 to Janese in view of U.S. Patents 4,903,707 to Knute et al. and 4,830,849 to Osterholm. Janese does not teach that the pH probe is inserted into a patient's brain ventricle. Janesen teaches that the apparatus is used to exchange cerebrospinal fluid. (column 2, lines 42-43 of Janese). It is well known in the art that cerebrospinal fluid is located in brain ventricles. Devices can be adapted for monitoring (as disclosed by Knute et al.) and treating (as disclosed by Osterholm) cerebrospinal



Art Unit: 3736

fluid in brain ventricles. The brain ventricles are considered suitable sites for monitoring and treatment and are functionally equivalent to the spinal cavity as disclosed by Janesen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the brain ventricle measurement and treatment site for the spinal cavity treatment site since they are functionally equivalent and it has generally been held to be within the skill level of the art to substitute measurement sites that are functionally equivalent.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,704,352 to Tremblay et al. discloses an implantable biosensor for monitoring pH in a brain ventricle. Article "Cerebrospinal fluid lactate and pH in patients with acute severe head injury" by Enevoldsen et al which discloses that CSF lactate and pH during the post-traumatic period may be a valuable tool in the assessment of the course and outcome of brain injury. Article "The continuous measurement of cerebrospinal fluid gas tensions in critically ill neurosurgical patients: a prospective observational study" by Venkatesh et al which discloses that CSF gas tensions and pH values may be an indicator of cerebral perfusion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

Art Unit: 3736

0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer  
Assistant Examiner  
Art Unit 3736  
February 14, 2002



ERIC F. WINAKUR  
PRIMARY EXAMINER